# Dyslipidemia in Japanese Patients with Rheumatoid Arthritis

Submission date Recruitment status Prospectively registered 02/06/2010 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 29/06/2010 Completed [ ] Results [ ] Individual participant data **Last Edited** Condition category [ ] Record updated in last year 29/06/2010 Musculoskeletal Diseases

## Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers N/A

# Study information

Scientific Title

Dyslipidemia in Japanese Patients with Rheumatoid Arthritis: A Retrospective Multicentre Observational Study

#### **Study objectives**

By investigating the prevalence of dyslipidemia and its relationships with disease activity, or medical interventions, it is possible to reduce subsequent mortality and morbidity of cardiovascular disease in patients with rheumatoid arthritis (RA).

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

The Institutional Review Board of the Kyushu University School of Medicine approved on the 10th of May 2010

#### Study design

Retrospective multicentre observational study

#### Primary study design

Observational

#### Secondary study design

Cohort study

#### Study setting(s)

Hospital

# Study type(s)

Screening

# Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

# Health condition(s) or problem(s) studied

Rheumatoid arthritis

#### **Interventions**

Non-interventional, observational study.

The blood samples from a cohort of patients being treated with lipid-lowering drugs will be taken at baseline, 2, 4, 6, 8 months after administration.

Information will be collected on the patient's history of cardiovascular events.

## Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome measure

- 1. To investigate the lipid profile and estimate the prevalence of dyslipidemia
- 2. To determine the relationships between the lipid profiles and the RA disease activity, or the treatments such as Disease Modifying Antirheumatic Drugs (DMARDs), biologics, glucocorticoids.

#### Secondary outcome measures

To investigate the effect of administered statins in the treatment of dyslipidemia in Japanese patients with RA.

#### Overall study start date

01/06/2009

#### Completion date

31/03/2013

# **Eligibility**

#### Key inclusion criteria

- 1. Age > 18 yrs
- 2. Fulfilled the 1987 revised criteria for RA of the American College of Rheumatology
- 3. Access to medical record information

#### Participant type(s)

**Patient** 

#### Age group

Adult

## Lower age limit

18 Years

#### Sex

Both

# Target number of participants

500

#### Key exclusion criteria

History of medical conditions other than RA which may affect lipid profile

#### Date of first enrolment

01/06/2009

#### Date of final enrolment

31/03/2013

# Locations

## Countries of recruitment

Japan

## Study participating centre Maidashi 3-1-1 Fukuoka Japan 812-8582

# Sponsor information

#### Organisation

Kyushu University (Japan)

#### Sponsor details

Department of Orthopaedic Surgery Graduate School of Medical Sciences Maidashi 3-1-1 Higashi-ku Fukuoka Japan 812-8582

#### Sponsor type

University/education

#### **ROR**

https://ror.org/00p4k0j84

# Funder(s)

#### Funder type

University/education

#### Funder Name

Graduate School of Medical Sciences, Kyushu University (Japan) - Department of Orthopaedic Surgery

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

Intention to publish date
Individual participant data (IPD) sharing plan

**IPD sharing plan summary**Not provided at time of registration